HFI-35 Received 11/21/96 ML. Rose d1510b

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1110182

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

November 15, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. J. Michael Shackelford, President
York River Seafood Co., Inc.
P.O. Box 239, Route 1102
Hayes, Virginia 23072

Dear Mr. Shackelford:

During an inspection of your facility conducted by the Food and Drug Administration (FDA) on October 22, 1996, deviations from the Good Manufacturing Practice Regulations (GMP), (Title 21, Code of Federal Regulations (CFR), Part 110), were documented with respect to your firm's crabmeat processing operation. By virtue of these deviations, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Our inspection revealed that insanitary conditions noted during previous inspections of your facility are continuing. These include, among other deviations listed on the FDA-483 presented to you at the conclusion of the inspection, the presence of live flies on crabmeat in the packing room; condensate water from overhead cooling units dripping onto whole cooked crabs; failure to calibrate and/or document the calibration of the temperature recording device used in the pasteurization of crabmeat; failure to have mercury-in-glass thermometers available to verify pasteurization temperatures; failure to control the supply of cooked crabs, and the weighing and packing of crabmeat in a manner that maintains the temperature of the product at levels suitable to retard the growth of microorganisms; failure to adequately clean and sanitize picking tables; and failure to conduct and/or document can seam examinations on a regular basis.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, Suite 424, 10710 Midlothian Turnpike, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,

Kenneth C. Shelin
Director, Baltimore District

cc: Virginia State Department of Health
Bureau of Shellfish Sanitation
1500 East Main Street, Room 214
Richmond, Virginia 23218